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June 3, 2005

VIA UPS DELIVERY

Michael Sciucco, Esq.  
ITV Direct, Inc.  
900 Cummings Center, B07u  
Beverly, MA 01915

Re: Sea Vegg Dietary Supplement

Dear Mr. Sciucco:

I am writing to advise you that the Electronic Retailing Self-Regulation Program ("ERSP") has concluded its inquiry and to enclose the final case decision.

In accordance with section 3.1 of ERSP Policy and Procedures, we request you add a Marketer's Statement to the final case decision. The Marketer's Statement is a short, concise response that must include a declaration whether the market agrees to accept ERSP's decision in its entirety and agrees to modify the advertising.

We request this Statement in writing as soon as possible, but must have it no later than 4:00 p.m. [eastern time] on Friday, June 10, 2005. Shortly after that time, we will release the final case decision with the Marketer's Statement to the press.

If we do not receive a Marketer's Statement by that time, we will conclude that the attempts to resolve questions by the self-regulatory route have failed. Following the Procedures, the advertising will be referred to an appropriate government agency. ERSP hopes you are willing to complete the process and take our enclosed recommendations into consideration in your future advertising.

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Please call me immediately at (212) 705-0126 if you have questions or comments on the Procedures or the language of the decision. ERSP does not have discretion to modify the time restraints.

I hope the guidance provided by this forum was helpful and we greatly appreciate your participation in the ERSP self-regulation program.

Sincerely,



Peter C. Marinello  
Director

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**ITV DIRECT, INC.**  
***Sea Vegg Nutritional Supplement***

### BASIS OF INQUIRY

Direct response advertising for the Sea Vegg nutritional supplement marketed by ITV Direct, Inc. ("ITV") came to the attention of the Electronic Retailing Self-Regulation Program ("ERSP") pursuant to its routine monitoring program. The thirty-minute, long-form (i.e., infomercial) direct response advertisement is presented in the form of an ongoing ITV program and is hosted by Donald Barrett who conducts a program-length discussion with product developer Scott Kennedy. ERSP identified the following core claims made in the infomercial as the basis of inquiry.

#### 1. General Performance Claims

- "...many chronic degenerative diseases can be prevented and reversed from products that come from the ocean."
- "Let their body regenerate"
- "Seaweed can help people get stronger."
- "I haven't had a cold, flu, or fever since 1992...because my PH is balanced with seaweed."
- "There's an 86 year old dog has come back to life."
- "...rebalances the thyroid."
- "Chronic fatigue...auto immune malfunction...you feel stamina."
- "...helped my mother's MS."
- "...couldn't believe that one supplement could do all those things."
- "...the most nutritionally potent and mineral rich family of plants on earth."

#### 2. Weight-Loss Claims

- "Stabilize your weight...despite your eating habits."
- "Used to assist in weight loss."

#### 3. Ingredient Claims

- "76% of all the oxygen on the planet comes from a seaweed plant."
- "Our blood plasma is identical to sea water."
- "Removes toxins and heavy metals"
- "60 times pound for pound the nutritional density of a land plant salad."
- "We have chosen species with higher minerals and capacities."

**CONFIDENTIAL****4. Health and Safety Claims**

- "Chronic degenerative disease...should they take more? [yes] so don't worry about OD'ing."
- "Put your multivitamin aside"
- "Incredibly, the destruction of these [cancerous] tumors was observed to take place without affecting normal cells."

**5. Establishment Claims**

- "scientific agreement behind my message and my mission"
- "Sea Vegg regenerates your body like nothing else on earth...rebuilding...and the science proves it."
- "scientific research to back up."
- "We've been studying it for 20 years"
- "scientific agreement on the value of sea vegetation when ingested into the human body."
- "We have all the science behind it."

**MARKETER'S POSITION**

ITV respectfully disagreed with ERSP's analysis of the direct response advertisement, stating that "... a reasonable interpretation of the advertisement would not link many of the statements you have identified to the product Sea Vegg itself but rather to sea vegetation or seaweed in general." While it agreed with ERSP that the advertisement is for Sea Vegg and not seaweed, it also stated that a reasonable consumer would not associate the claims identified by ERSP with any specific properties of the Sea Vegg nutritional supplement.

The marketer explained that Sea Vegg is a blend of up to 12 specific species chosen from over 10,000 sea plants worldwide for their full-light nutritional spectrum qualities and that the product provides hundreds of organic compounds and is toxin free synthetic. Unlike a synthetic drug or supplement, Sea Vegg is similar to a whole food, the minerals and nutrients contained in the product are naturally occurring and their amounts vary according to harvest cycle. The marketer added that advertisement does not espouse the benefits of Sea Vegg, but rather sea vegetation.

According to the marketer, it possesses reliable and competent data "which comprise a combination of controlled clinical studies, scholarly journal articles, research papers, consumer testimonials and other materials which speak both to the efficacy and safety of sea vegetation." The marketer maintained that this evidence adequately substantiates the claims made in its advertising and while agreeing that the

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burden is on the marketer to support any reasonable interpretations of claims made in the advertisement, it maintained that advertisers are not required to possess studies on the product itself, but should only be required to reasonably substantiate the claims made in the advertisement, which it believes it has done.

#### 1. General Performance Claims

The marketer informed ERSP that some of the claims specified in the Basis of Inquiry (i.e., "any degenerative disease can be prevented and reversed from products that come from the sea.") were inaccurately characterized (i.e., "many of our degenerative disease can be prevented and reversed from nutrients that come from the ocean.") and explained that there is a growing body of evidence which demonstrates that sea vegetation is useful in preventing and reversing a number of degenerative diseases, although the direct response advertisement does not impliedly or expressly state that Sea Vegg is an effective treatment, preventative or cure for any disease. As further information for the consumer, the advertisement clearly and prominently displays the standard DSHEA disclaimer ("This product is not intended to diagnose, treat, cure or prevent any disease") in text at the beginning and end of the advertisement.

##### a. Carcinogenesis

ITV maintained that a number of studies demonstrate that sea vegetation inhibits carcinogenesis. Two studies were submitted by the marketer indicating that edible seaweed has "*drastic anti-mutagenic activity*" and a similar type of edible seaweed was shown to have up to 96% inhibition of mutagenicity. The marketer also called ERSP's attention to a study conducted on rats which showed that test subjects fed seaweed for 152 days exhibited a significant delay in time to tumorigenesis after high exposure to high levels of carcinogens as compared to the control group.

ITV disputed ERSP's assertion that it has stated in the advertisement that Sea Vegg inhibits carcinogenesis. Nevertheless, it maintained that the information it provided indicates that "*nutrients from the ocean*" have benefits for chronic disease and it submitted competent and reliable scientific evidence to ERSP as support for those statements. ITV asserted that it believes the representations, understood in their true context and correctly stated, coupled with the totality of the evidence, are entirely appropriate and are not misunderstood by consumers.

ITV asserted that sea vegetation has also been shown to limit tumor growth and metastasis. According to the marketer, "*the Yamamoto lab has reported that when tumors were implanted into rats that were fed seaweed, the growth of the tumors was inhibited by up to 95.2%*." Similarly, scientists at the Nagoya School of Medicine

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report that rats fed seaweed showed "significant suppression of tumor growth" post carcinogen exposure. A wide range of studies have demonstrated fucans (constituents of seaweed) to be potential inhibitors of experimental metastasis and this result is confirmed by an in-vivo experiment in which mice who were given fucoidan showed significant inhibition of metastasis when tumors were introduced. According to ITV, the data it provided demonstrates that seaweed, in general, has many benefits. Fucoidan is only one constituent of seaweed; there are many other naturally occurring "ingredients" of seaweed. According to the marketer, Sea Vegg is not a fucoidan or carrageenan product, it is a seaweed product and the benefits of seaweed are well documented and have a long history of traditional use.

The marketer maintained that, in addition to slowing or preventing cancers, there is also evidence that sea vegetation may be able to reverse the course of the disease and actually kill existing tumor cells and called ERSP's attention to two scientific reports indicating that edible seaweed exhibits a strong cytotoxic [cell killing] effect on human tumor cells. The marketer added that several other animal studies also support this premise.

*b. Cardiovascular disease*

Cardiovascular disease is any disease of the heart and blood vessels which many doctors and experts believe to be the number one killer in the United States. Scientists have recently focused on fucoidan, a seaweed constituent, as a possible agent to combat these afflictions. ITV maintained that a recent study has demonstrated that rats who received fucoidan and were suffering from a constriction or blockage of the arteries "significantly improved blood flow." According to the marketer, fucoidan has similarly been shown to reduce the growth of vessel wall caused by reduced blood flow by 59% in rabbits.

*c. Regenerative diseases*

Regarding the claims of allowing the body to regenerate, the marketer stated that any fruit or vegetable that is ingested into the human body has some regenerative qualities and disputed ERSP's interpretation of the claims, noting that Scott Kennedy, the spokesman in the infomercial, goes on to state that Sea Vegg doesn't regenerate the body - the body regenerates itself. Alternatively, ITV argued that the claim is puffery.

The marketer informed ERSP that its strength claims were supported by virtue of the "high level of protein in seaweed which is essential in building muscle" and that Scott Kennedy's claim of not having a cold in almost 15 years (presumably because of his daily seaweed intake) is "essentially unmeasurable." ITV noted that

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its claim of an 86 year old dog being brought back to life after eating a daily dosage of seaweed is based on a true account submitted by a consumer.

*d. Other Diseases*

ITV alleged that ERSP misquoted its chronic fatigue claim and noted that the claim that seaweed "*helped my mother's MS*" was clearly a statement of opinion. The marketer maintained that the data it provided substantiates the premise that sea vegetation has properties that do, in fact, prevent or reverse disease, although it contended that the advertisement does not impliedly or expressly state that Sea Vegg has such qualities. ITV also referred to two DSHEA disclaimers which it maintained are clearly and prominently displayed, with supers at the beginning and end of the advertisement with voiceovers to prevent any confusion.

Additionally, ITV alluded to reports that seaweed extract inhibited the cytopathic effect of the HIV-1 virus on immune system cells and stated that other studies have confirmed that carrageenan (found in seaweed) is a potential inhibitor of HIV. The marketer also submitted several studies which discuss the association of seaweed with diminishing HIV characteristics.

The marketer contended that several studies have confirmed that sulphated polysaccharides isolated from seaweed are potent inhibitors of the Herpes Simplex Virus. Moreover, the marketer maintained that it possesses data indicating that "*it is a matter of scientific consensus*" that sea vegetables are potent ant-viral agents.

With respect to its antibiotic and antifungal properties, the marketer stated that research has demonstrated that seaweed extracts and its constituents provide a certain degree of protection from many bacterial species and pathogenic yeasts and fungus.

*2. Weight Loss Claims*

According to ITV, increasing the intake of iodine and selenium has been shown to increase serum thyroid hormone levels in humans. The marketer submitted one study which demonstrated that patients with the greatest degree of thyroid suppression experienced the greatest gain in weight and "[G]iven the fact that iodine stimulates the thyroid gland, it is reasonable to conclude that eating foods rich in iodine (seaweed) could lead to weight loss." The marketer also alluded to the prevalence of seaweed wraps on the market, noting that they are commonly known for their ability to help with weight loss.

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With respect to the specific weight claims (i.e., "Stabilize your weight... despite your eating habits."), the marketer stated that the representations in the infomercial were qualified by the disclosure "Results may vary. Consult a doctor before beginning any nutritional program" and the statements reflected the biological action of certain materials in seaweed "*at the rate at which the body metabolizes fats and sugars.*" The marketer added that a reasonable consumer would not expect to lose a specific amount of pounds by taking Sea Vegg because a quantitative figure of weight loss is not stated in the advertisement. However, the initial "Results May Vary" disclosure clearly demonstrates only that seaweed and its organic components help with weight loss.

### 3. Ingredient Claims

ITV maintained that its voluminous submission of research on the ingredients contained in seaweed clearly provides adequate support for its claims regarding the potency and therapeutic qualities of the particular ingredients contained in each Sea Vegg capsule.

Further, the marketer referred to the *Encyclopedia Britannica* to support its claim that "*76% of all oxygen on the planet comes from the seaweed plant*" and maintained that its claim "*Our plasma is identical to seawater*" reflects an issue of common consensus in the scientific community.

ITV also asserted that a number of studies have shown that vegetation from the sea removes toxins and heavy metals; fucoidan has been shown to decrease muscle damage; alginic acid (a constituent of seaweed) has lowered magnesium absorption and fresh seaweed has provided therapeutic benefits for copper toxicity and a reducer of plasma methyl mercury activity.

While contending that the anti-tumor properties of seaweed are well documented in several scientific studies and that sea vegetation can have "*up to 60 times the density by weight of certain clinical nutrients as compared to land plants,*" the marketer stated that the seaweed blend used in Sea Vegg is of significant mineral and nutritional content.

### 4. Health and Safety claims

The marketer alluded to the lack of any reported deaths due to seaweed over the years and also called ERSP's attention to a recent article which discussed the safe doses of fucose (i.e., 34 grams per day), an amount that is well below the amount of fucose contained in the product.

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With respect to the claim that consumers can now "put your multivitamin aside," ITV stated the claim is supported because "the nutritional value of seaweed is well documented and has many, if not all, of the vitamins and minerals as your average multivitamin."

ITV argued that there is significant data to support its claim that "*sea vegetation and the iodine in it can help rebalance the thyroid*" because it is an accepted fact that sea vegetation is a rich source of iodine. The marketer referred to a study it submitted showing that test subjects who consumed iodine in their diets for 1-2 months significantly increased the functioning of their thyroids and may have exhibited a protective effect on the thyroid from radiation.

#### 5. Establishment Claims

The marketer stated that the claim that there is "*scientific agreement behind my message and mission:*" is substantiated by virtue of the voluminous materials provided by ITV and that sea vegetation has been the subject of scientific research dating back centuries.

The marketer re-iterated that the constituents in seaweed and Sea Vegg are naturally occurring and vary according to harvest cycle, and thus clinical testing on the "*ingredients*" and the amounts of ingredients contained in Sea Vegg would be unduly burdensome. The data, as it relates to sea vegetation and Sea Vegg and its naturally occurring constituents, cannot be characterized as dubious, but is the exact opposite and very clear. Seaweed in any form has extraordinary properties.

The marketer contended that indications, methodologies and administrations of the studies presented on seaweed vary and are in-vivo, in-vitro, on humans and on animals. The infomercial spokesperson expressly informs the reasonable consumer that most of the studies were on animals. The marketer reiterated to ERSP that "*most if not all of the drugs on the market begin testing on animals and many have been brought to market without human testing.*"

#### **ANALYSIS**

ITV provided ERSP with an abundance of information on the benefits of seaweed which was presented in the form of animal testing abstracts, scientific research and various industry publications. ERSP does not dispute the potential general health benefits that may be provided by a long-term, carefully administered diet of seaweed. As noted in several of the publications offered by ITV, the encouraging information undeniably merits further research and evaluation. Notwithstanding the volume of information provided by ITV, ERSP was

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troubled by the communication of very specific and dramatic health and performance claims for the product that were based on the extrapolation of ingredient data to the Sea Vegg product despite the fact that the marketer did not conduct any studies on the advertised product, nor did it conduct testing on the ingredients at the same strength/concentration in which they are contained in the product.

#### 1. General Performance Claims

An advertiser or marketer has the burden to support *any* reasonable interpretation of its advertising, and because the direct response advertisement at issue is clearly a commercial message intended to induce the sale of Sea Vegg dietary supplements (and not "seaweed"), ERSP determined that there can be very little dispute that many of the claims for seaweed (which the marketer maintained were simply representations regarding the benefits of "sea vegetation") will be reasonably understood by consumers as being attributable to Sea Vegg. In addition to the context in which the claims were presented in the advertisement, the fact that a bottle of Sea Vegg capsules are prominently displayed throughout the infomercial further contributed to ERSP's determination regarding a reasonable consumer take away.

During the pendency of the inquiry, ITV provided ERSP with over 100 exhibits which the marketer maintained demonstrated the many health advantages of the different types of seaweed and the ingredients contained therein (i.e., iodine, fucoidan, etc.). Moreover, while relying on this information as support, the marketer communicated several express health benefits that come with consuming sea vegetation (i.e., Sea Vegg) including weight loss, preventing and reversing "most degenerative diseases," assisting with multiple sclerosis, increasing strength and stamina, rebalancing the thyroid and inhibiting carcinogenesis. However, because the advertised product is admittedly a *blend* of up to 12 different seaweed species, it is virtually impossible to ascertain the potency of each Sea Vegg capsule and even the marketer cannot be sure which of the 10,000 sea plant varieties is contained in an individual capsule, much less the strength of a particular ingredient that may be contained in one of the blended "species." Further, despite the unmistakable association being made in the advertisement between the benefits of seaweed and the Sea Vegg capsules, ITV provided no testing or evaluation on the product itself nor could it confirm that any of the ingredients of Sea Vegg tested were evaluated at the same concentration level as they are contained in the advertised product.

ERSP does not disagree with the marketer's position that it is not required by law to provide testing of its product to substantiate product performance claims made in its advertising. However, in the omission of such evidence, the marketer

must be prepared to demonstrate that the individual ingredients of the product that were tested were of the same (or similar) strength and quality as they are contained in the product. Particularly when an advertiser or marketer is making health or safety claims, this is the standard used to determine whether the evidence can be considered competent and reliable in a manner that is consistent with the general standards used in the industry. The marketer's position that conducting such testing would be unduly burdensome is no justification for not having substantiating evidence to support its claims.

Accordingly, having determined that consumers could associate the attributes and benefits of seaweed to the advertised product, ERSP concluded that the failure of ITV to provide testing on the advertised product or confirmation that the ingredients of Sea Vegg were tested at the same strength at which they are contained in the product, was a fatal flaw and that the evidence did not provide adequate substantiation for the general performance claims at issue.

## 2. Weight-Loss Claims

Although the weight loss claims made in the infomercial were limited to a few isolated representations (i.e., "Stabilize your weight...despite your eating habits."); "Used to assist in weight loss."), ERSP was concerned with the marketer's attempt to position the product as one which will facilitate weight-loss – particularly in the absence of any testing on the product to verify any weight loss to consumers. The contention that a consumer could lose or stabilize weight "despite your eating habits" is also unsupported.

While ITV did note that a small disclaimer appears in the infomercial stating that "Results may vary. Consult a doctor before beginning any nutritional program," ERSP concluded that this disclaimer does little to qualify the weight loss claim because without any testing indicating the what the typical result of weight loss would be from taking the product, it is of little meaning to consumers that there may be a variance from what they should expect.

Lastly on this issue, it was also the marketer's position that weight loss is based on the fact that minerals in seaweed metabolize fats and sugars, as well as the fact that increases in iodine (also found in seaweed) increase the rate of metabolism which, in turn, decreases thyroid function which has been shown to be "inversely related to weight gain." ERSP determined that while this explanation may, in fact, be theoretically plausible, the absence of any direct correlation between the amount of the minerals (i.e., iodine) in seaweed and the existence of the minerals in Sea Vegg renders the marketer's position untenable and inadequate to support any potential assertions regarding the weight loss

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capacity of Sea Vegg. Accordingly, any weight loss claims for Sea Vegg should be discontinued.

### 3. Health and Safety Claims

Of course, the fact there have been "no reported deaths due to seaweed over thousands of years" is a noteworthy and compelling statistic but, again, it cannot be ignored that there has been no testing on either the efficacy or the safety profile of this product. ERSP determined that some of the very aggressive health assertions made in the advertising (such as consumers putting their multivitamins aside), are simply unwarranted. It was further concluded that implied claims by Scott Kennedy that because he has taken Sea Vegg, he hasn't "...had a cold, flu, or fever since 1992...." and that "an 86 year old dog has come back to life" only contribute to the ambiguous message being communicated to consumers.

Lastly, the suggestion that Sea Vegg will help alleviate serious health problems such as chronic degenerative disease and fatigue, and will rebalance the thyroid are unsupported and should be discontinued from future advertising.

### 4. Ingredient Claims

The marketer made several factual assertions regarding the general potency of ingredients contained in seaweed and ERSP does not dispute the beneficial qualities of seaweed and its biological significance in the ecosystem. However, the marketer should be careful not to embellish the importance of seaweed through categorical (and inaccurate) representations such as "our plasma is identical to seawater"; "60 times pound for pound the nutritional density of a land plant salad" and "76% of all the oxygen on the planet comes from seaweed." While ERSP does appreciate the efforts of the marketer to provide substantiation for these claims, the fact remains that the relevancy to consumers of such representations - as they pertain to Sea Vegg, the advertised product - is uncertain.

While the marketer has attempted to disassociate many of its aggressive claims about seaweed from the advertised product, ERSP determined that, to a large extent, the implications being taken by consumers regarding the advertised product are simply unavoidable. It is almost implausible to divorce many of touted attributes of "sea vegetation" from "Sea Vegg." In essence, the marketer spends thirty minutes discussing the unparalleled characteristics of seaweed, then tells consumers that it has "chosen species with the highest minerals and capacities" and that Sea Vegg is "even better than" seaweed because its composed of a blend of 12 different "species" of sea vegetation and subsequently maintains that it would be unreasonable for consumers to link its ingredient claims to the advertised product.

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Following the legal premise that an advertiser has the burden of supporting any reasonable interpretation of its claims, ERSP determined that this argument is untenable and that the infomercial should be modified to prevent such a consumer take-away from claims about the individual ingredients contained in Sea Vegg.

#### 5. Establishment Claims

Although ERSP has recommended that the marketer either modify or discontinue many of the general performance, weight loss, safety and ingredient claims made in the direct response advertisement, we do recognize the volume of evidence and scientific research on many of the individual ingredients in seaweed. So long as the marketer can clearly communicate that its scientific research: a) is limited to the ingredients contained in seaweed and b) should not be construed as meaning that consumers should expect the ingredients, as they are contained in Sea Vegg, to provide the same benefits, ERSP does not object to references to the scientific research on seaweed.

However, it was determined that claims such as "there is scientific research behind it" and "we've been studying it for 20 years" can be reasonably interpreted by consumers as pertaining to Sea Vegg. ITV cannot support such an interpretation and the claims should be modified accordingly.

#### **CONCLUSION**

An advertiser or marketer has the burden to support any reasonable interpretation of its advertising and ERSP determined that many of the claims made by ITV will be reasonably understood by consumers as being attributable to Sea Vegg. However, the marketer did not conduct any studies on the advertised product nor did it conduct testing on the ingredients at the same strength in which they are contained in the product and, as such, ERSP concluded that the marketer could not support the claims of general product performance, health and safety and weight loss. ERSP was also concerned that many of the claims made by ITV that were based on the testing of individual ingredients in Sea Vegg would be understood by consumers as being attributable to the advertised product when, in fact, they are not. Lastly, ERSP did not object to references to the scientific research on seaweed, but suggested that ITV clarify to consumers that its research is limited to ingredients in seaweed and should not be understood as being applicable to Sea Vegg.

As such, ERSP recommends that ITV either make substantial and significant modifications to the advertising or discontinue the advertising completely.

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**MARKETER'S STATEMENT**